

Shar
on E.

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE Kennedy
FORM PTO-146

Digitally signed by
o=USPTO,
DN: cn=Sharon E.

Sheet 1 of 1

Kennedy, c=US, **LIST OF ART CITED BY APPLICANT**

| | | |
|--------------|-------------------------------------|---|
| ATTY. DOCKET | 17-59-CON2-CIP1-CIP1 (BOT) | SERIAL NO.: 10/752,871 |
| APPLICANT | SHARON E. KENNEDY | TITLE: INTRAVITREAL BOTULINUM TOXIN IMPLANT |
| FILING DATE | JANUARY 20, 2006 10:17:20-06-04'00' | GROUP: 1615 |

U.S. PATENT DOCUMENTS

| *EXAMINER INITIAL | DOCUMENT NO. | DATE | NAME | CLASS | SUB-CLASS | FILING DATE (if applicable) |
|-------------------|--------------|------|------|-------|-----------|-----------------------------|
| AA | | | | | | |
| AB | | | | | | |
| AC | | | | | | |
| AD | | | | | | |
| AE | | | | | | |

FOREIGN PATENT DOCUMENTS

| | DOCUMENT NO. | DATE | COUNTRY | CLASS | SUB-CLASS | TRANSLATION (yes/no) |
|---------|--------------|-----------|---------|-------|-----------|----------------------|
| /SK/ BA | WO99/37326 | 29JUL1999 | PCT | A61K | 9/16 | Y |
| | BB | | | | | |
| | BC | | | | | |
| | BD | | | | | |
| | BE | | | | | |
| | BF | | | | | |

OTHER ART
(Including Author, Title, Date, Pertinent Pages, etc.)

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| /SK/ CA | JANKOVIC J et al., "Botulinum toxin treatment of tremors", <u>Neurology</u> , vol. 41, no. 8, August 1991, pp. 1185-1188 |
| /SK/ CB | MAYSINGER D et al., "Preparation and in vivo effect of microencapsulated cholinotoxin", <u>International Journal of Pharmaceutics</u> , vol. 63, no. 2, 15 September 1990, pp. 149-154 |
| /SK/ CC | MEN Y et al., "A single administration of tetanus toxoid in biodegradable microspheres elicits T cell and antibody responses similar or superior to those obtained with aluminum hydroxide", <u>Vaccine</u> , vol. 13, no. 7, 1995, pp. 683-689 |
| /SK/ CD | |
| /SK/ CE | |
| /SK/ CF | |

EXAMINER /Sharon Kennedy/

DATE CONSIDERED 05/10/2007

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Sharon E.
Kennedy

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PATENT AND TRADEMARK OFFICE
FORM 1461
105 E. PAISLEY, PORTLAND, OREGON 97232



Sheet 1 of 6

LIST OF ART CITED BY APPLICANT

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|---|---|
| ATTY. DOCKET: 17359CON2CIP1CIP1 (BOT) Digitally signed by Sharon E. Kennedy | SERIAL NO.: 10/752,871 |
| DAPPEL, Sharon E. Kennedy, Stephen J. Donovan c=US, o=USPTO, ou=1615 email=sharon.kennedy@uspto.gov | TITLE: INTRAVITREAL BOTULINUM TOXIN IMPLANT |
| FILING DATE: January 6, 2004 | GROUP: 1615 |

Date: 2007.05.10 17:18:22 -04'00'

U.S. PATENT DOCUMENTS

| *EXAMINER INITIAL | DOCUMENT NO. | DATE | NAME | CLASS | SUB-CLASS | FILING DATE (if applicable) |
|-------------------|-----------------|------|------|-------|-----------|-----------------------------|
| /SK/ AA | 2003-0095995 | | | | | |
| | AB 3,523,906 | | | | | |
| | AC 3,691,090 | | | | | |
| | AD 3,737,337 | | | | | |
| | AE 3,773,919 | | | | | |
| | AF 4,389,330 | | | | | |
| | AG 4,767,628 | | | | | |
| | AH 5,019,400 | | | | | |
| | AI 5,437,291 | | | | | |
| | AJ 5,501,856 | | | | | |
| | AK 5,667,808 | | | | | |
| | AL 5,670,484 | | | | | |
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| | AN 5,766,605 | | | | | |
| | AO 5,902,565 | | | | | |
| | AP 5,980,945 | | | | | |
| | AQ 5,980,948 | | | | | |
| | AR 6,007,843 | | | | | |
| | AS 6,011,011 | | | | | |
| | AT 6,022,554 | | | | | |
| | AU 6,063,768 | | | | | |
| | AV 6,113,915 | | | | | |
| | AW 6,139,845 | | | | | |
| | AX 6,143,306 | | | | | |
| | AY 6,265,379 | | | | | |
| | AZ 6,299,893 | | | | | |
| | AAA 6,306,403 | | | | | |
| | ABB 6,306,423B1 | | | | | |
| ▼ | ACC 6,312,708 | | | | | |
| /SK/ ADD | 6,328,977 | | | | | |

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|------|-----|-------------|--|--|--|--|--|
| /SK/ | AEE | 6,358,513 | | | | | |
| | AFF | 6,365,164B1 | | | | | |
| | AGG | 6,383,509B1 | | | | | |
| | AHH | 6,395,277 | | | | | |
| | AII | 6,423,319 | | | | | |
| | AJJ | 6,458,365 | | | | | |
| ↓ | AKK | 6,464,986 | | | | | |
| | ALL | 6,699,493 | | | | | |
| /SK/ | AMM | 6,726,918 | | | | | |

FOREIGN PATENT DOCUMENTS

| | | DOCUMENT NO. | DATE | COUNTRY | CLASS | SUB-CLASS | TRANSLATION (yes/no) |
|------|----|--------------|------|---------|-------|-----------|-------------------------|
| /SK/ | BA | EP 654,256 | | | | | |
| | BD | | | | | | |

OTHER ART
(Including Author, Title, Date, Pertinent Pages, etc.)

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| /SK/ | CA | am Ende, M.T. et al., <i>Factors influencing drug and protein transport and release from ionic hydrogels</i> , Reactive Polymers, 25 (1995);127-137 |
| /SK/ | CB | Aoki K.R., Cui M, <i>Mechanisms of the Antinociceptive Effect of Subcutaneous BOTOX®: Inhibition of Peripheral and Central Nociceptive Processing</i> , Cephalgia 23(7);649:2003 |
| /SK/ | CC | Aoki K.R., <i>Pharmacology and immunology of botulinum toxin serotypes</i> , J Neurol 248(suppl 1);I/3 –I/10:2001 |
| /SK/ | CD | Argoff, A <i>Focused Review on the Use of Botulinum Toxins for Neuropathic Pain</i> , Clin J Pain (2002) 18(6 Suppl);S177-S181 |
| /SK/ | CE | Bell, C. et al., <i>Poly(methacrylic Acid-g-Ethylene Glycol) Hydrogels as pH Responsive Biomedical Materials</i> , Mater Res Soc Symp Proc (1994), 331;199-204 |
| /SK/ | CF | Bigalke H., et al., <i>Botulinum A Neurotoxin Inhibits Non-Cholinergic Synaptic Transmission in Mouse Spinal Cord Neurons in Culture</i> , Brain Research 360 (1985);318-324 |

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| /SK/ | CG | Bigalke H., et al., <i>Tetanus Toxin and Botulinum A Toxin Inhibit Release and Uptake of Various Transmitters, as Studied with Particulate Preparations From Rat Brain and Spinal Cord</i> , Naunyn-Schmiedeberg's Arch Pharmacol 316 (1981);244-251 |
| | CH | Binz T. et al., <i>The Complete Sequence of Botulinum Neurotoxin Type A and Comparison with Other Clostridial Neurotoxins</i> , J Biological Chemistry 265(16);9153-9158 (1990) |
| | CI | Brazel C. et al., <i>Temperature- and pH- Sensitive Hydrogels for Controlled Release of Antithrombotic Agents</i> , Mater Res Soc Symp Proc (1994), 331;211-216 |
| | CJ | Bushara K., <i>Botulinum toxin and rhinorrhea</i> , Otolaryngology - Head Neck Surg 1996;114(3):507 |
| | CK | Cardamone M., et al., <i>In Vitro Testing of a Pulsatile Delivery System and its In Vivo Application for Immunization Against Tetanus Toxoid</i> , J Controlled Release 47;205-219:1997 |
| | CL | Cleland J.L., et al, <i>Development of a Single-Shot Subunit Vaccine for HIV-1: Part 4. Optimizing Microencapsulation and Pulsatile Release of MN rpg120 from Biodegradable Microspheres</i> , J Cont Rel 47;135-150:1997 |
| | CM | Cleland, J. et al., <i>Development of a Single-shot Subunit Vaccine for HIV-1. 5. Programmable in Vivo Autoboost and Long Lasting Neutralizing Response</i> , J Pharm Sci (1998) 87:1; 1489-95 |
| | CN | Cleland, Jeffrey L., <i>Solvent Evaporation Processes for the Production of Controlled Release Biodegradable Microsphere Formulations for Therapeutics and Vaccines</i> , Biotechnol Prog (1998), 14(1):102-7 |
| | CO | Coffield J., et al., <i>Site and Action of Botulinum Neurotoxin, Therapy With Botulinum Toxin</i> , Ed. Jankovic J. et al., Publ. Marcel Dekker, Inc., (1994), page 5 |
| | CP | Cui M, Aoki KR, <i>Botulinum toxin type A (BTX-A) reduces inflammatory pain in the rat formalin model</i> , Cephalgia 20(4);414:2000 |
| | CQ | Doeiker E., <i>Cellulose Derivatives</i> , Adv Polym Sci 107; 199-265:1993 |
| | CR | Dong, Liang-Chang et al., <i>A novel approach for preparation of pH-sensitive hydrogels for enteric drug delivery</i> , J. Contr Rel 15 (1991);141-152 |
| ↓ | CS | Durham P., et al., <i>Mechanism of botulinum toxin type-A Inhibition of Calcitonin Gene-Related Peptide Secretion from Trigeminal Nerve Cells</i> , Cephalgia (2003) 23(7);690 |
| /SK/ | CT | Garry, M. et al., <i>Evaluation of the efficacy of bioerodible bupivacaine polymer system on antinociception and inflammatory mediator release</i> , Pain 82 (1999);49-55 |

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|------|-----|--|
| /SK/ | CU | Gonelle-Gispert et al., <i>SNAP-25a and -25b isoforms are both expressed in insulin-secreting cells and can function in insulin secretion</i> , Biochem J. 339 (1999) (pt 1):159-165 |
| | CV | Habermann E. et al., <i>Tetanus Toxin and Botulinum A and C Neurotoxins Inhibit Noradrenaline Release From Cultured Mouse Brain</i> , J Neurochem (1988), 51(2):522-527 |
| | CW | Habermann E., <i>Inhibition by Tetanus and Botulinum A Toxin of the release of [³H]Noradrenaline and [³H]GABA From Rat Brain Homogenate</i> , Experientia 44 (1988);224-226 |
| | CX | Habermann, E., <i>I-Labeled Neurotoxin from Clostridium Botulinum A: Preparation, Binding to Synaptosomes and Ascent to the Spinal Cord</i> , Naunyn-Schmiedeberg's Arch. Pharmacol. 1974; 281, 47-56 |
| | CY | Hanes, J. et al., <i>New Advances in Microsphere-Based Single-Dose Vaccines</i> , Adv Drug Del Rev 28 (1997);97-119 |
| | CZ | Heller, <i>Biodegradable Polymers in Controlled Drug Delivery</i> , CRC Critical Reviews in Therapeutic Drug Carrier Systems, Vol. 1, Issue 1, Boca Raton, FL (1987); 39-90 |
| | CAA | Johansen P. et al., <i>Improving Stability and Release Kinetics of Microencapsulated Tetanus Toxoid by Co-Encapsulation of Additives</i> , Pharm Res 15:7(1998);1103-1110 |
| | CBB | Kissel et al., <i>Microencapsulation of Antigens Using Biodegradable Polymers: Facts and Fantasies</i> , Behring Inst. Mitt., 98 (1997);172-183 |
| | CCC | Kost, J. et al., <i>Magnetically enhanced insulin release in diabetic rats</i> , J. Biomed Mater Res (1987), 21;1367-1373 |
| | CDD | Langer, R. et al., <i>Polymers for Sustained Release of Proteins and Other Macromolecules</i> , Nature 263 (1976); 797-800 |
| | CEE | Langer, R., <i>New Methods of Drug Delivery</i> , Science 249 (1990);1527-1533 |
| | CFF | Lewis D. H., <i>Controlled Release of Bioagents from Lactide/Glycolide Polymers, Biodegradable Polymers as Drug-Delivery Systems</i> , Ed. Chasin M., et al., Marcel Dekker, New York (1990), pages 1-41 |
| | CGG | Mallapragada S.K. et al., <i>Drug Delivery Systems</i> , chapter 27, Ed. Von Recum, A. F. <i>Handbook of Biomaterials Evaluation</i> , second edition, Publ. Taylor & Francis (1999), 431-433 |
| ↓ | CHH | Marchese Ragona, R. et al., <i>Management of Parotid Sialocele With Botulinum Toxin</i> , The Laryngoscope 109 (August 1999):1344-1346 |
| /SK/ | | |

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| /SK/ | CII | Men Y. et al., <i>A Single Administration of Tetanus Toxoid in Biodegradable Microspheres Elicits T Cell and Antibody Responses Similar or Superior to Those Obtained with Aluminum Hydroxide</i> , Vaccine (1995) 13, 683-689 |
| | CJJ | Movement Disorders, Vol. 10, No. 3 (1995), pg. 376 |
| | CKK | Moyer E. et al., <i>Botulinum Toxin Type B: Experimental and Clinical Experience of "Therapy With Botulinum Toxin"</i> , edited by Jankovic, J. et al. (1994), Marcel Dekker, Inc., Chapter 6, pages 71-85 |
| | CLL | Naumann, M. et al., <i>Botulinum toxin type A in the treatment of focal, axillary and palmar hyperhidrosis and other hyperhidrotic conditions</i> , European J. Neurology (1999), 6 (Supp 4): S111-S115 |
| | CMM | Pearce, L.B., <i>Pharmacologic Characterization of Botulinum Toxin For Basic Science and Medicine</i> , Toxicon 1997; 35(9):1373-1412 at 1393 |
| | CNN | Powell, E. et al., <i>Controlled Release of Nerve Growth Factor from a Polymeric Implant</i> , Brain Res 1990;515(1-2):309-11 |
| | COO | Rao, Jyoti et al., <i>Implantable Controlled Delivery Systems for Proteins Based on Collagen – pHEMA Hydrogels</i> , Biomaterials 1994;15(5):383-9 |
| | CPP | Sanchez-Prieto, J. et al., <i>Botulinum Toxin A Blocks Glutamate Exocytosis From Guinea Pig Cerebral Cortical Synaptosomes</i> , Eur J. Biochem (1987) 165(3):675-681 |
| | CQQ | Schantz, E.J., et al, <i>Properties and use of Botulinum toxin and Other Microbial Neurotoxins in Medicine</i> , Microbiological Reviews (1992), 56(1):80-99 |
| | CRR | Schwendeman, S. et al., <i>Peptide, Protein, and Vaccine Delivery from Implantable Polymeric Systems-Progress and Challenges</i> , from Controlled Drug Delivery Challenges and Strategies, American Chemical Society (1997), Ed. Park K., chapter 12 (pages 229-267) |
| | CSS | Silberstein S. et al., <i>Botulinum toxin type A: Myths, facts, and current research</i> , Headache 2003 Jul;43 Suppl 1 1(Suppl 1);S1 |
| | CTT | Singh, <i>Critical Aspects of Bacterial Protein Toxins</i> , pages 63-84 (chapter 4) of <i>Natural Toxins II</i> , edited by B.R. Singh et al., Plenum Press, New York (1976) |
| ↓ | CUU | Sinha V. et al., <i>Bioabsorbable Polymers for Implantable Therapeutic Systems</i> , Drug Development and Industrial Pharmacy 24(12):1129-1138 (1998) |
| /SK/ | CVV | Sloop, R. et al., <i>Reconstituted botulinum toxin type A does not lose potency in humans if it is refrozen or refrigerated before 2 weeks before use</i> , Neurology 48 (January 1997):249-53:1997 |

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| /SK/ | CWW | Tobio M., et al., <i>A Novel System Based on a Poloxamer/PLGA Blend as a Tetanus Toxoid Delivery Vehicle</i> , Pharm Res (1999) 16(5):682-688 |
| /SK/ | CXX | Tracy et al., <i>Factors affecting the degradation rate of poly(lactide-co-glycolide) microspheres in vivo and in vitro</i> , Biomaterials 20 (1999):1057-1062 |
| /SK/ | CYY | USP 24; NF 19 (2000), pp. 1941-1951 |
| /SK/ | CZZ | Veronese, F.M. et al., <i>Polyorganophosphazene microspheres for drug release: polymer synthesis, microsphere preparation, in vitro and in vivo naproxen release</i> , Journal of Controlled Release 52 (1998):227-237 |
| /SK/ | CAAA | Weigand et al, <i>I-Labelled Botulinum A Neurotoxin: Pharmacokinetics in Cats after Intramuscular Injection</i> , Naunyn-Schmiedeberg's Arch. Pharmacol. 1976; 292, 161-165 |

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